

DARRYL M. WOO (CSB NO. 100513)  
CHARLENE M. MORROW (CSB NO. 136411)  
RYAN J. MARTON (CSB NO. 223979)  
C. J. ALICE CHUANG (CSB NO. 228556)  
DENNIS FAIGAL (CSB NO. 252829)  
FENWICK & WEST LLP  
555 California Street  
12th Floor  
San Francisco, CA 94104  
Telephone: (415) 875-2300  
Facsimile: (415) 281-1350

Attorneys for Defendants  
AMBU A/S, AMBU INC., AMBU LTD., and  
AMBU SDN. BHD.

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF CALIFORNIA

THE LARYNGEAL MASK COMPANY  
LTD. and LMA NORTH AMERICA,  
INC.,

Plaintiffs,

v.

AMBU A/S, AMBU INC., AMBU LTD.,  
and AMBU SDN. BHD.,

Defendants.

Case No. 3:07-cv-01988-DMS-NLS

Jury Trial Demanded

**DEFENDANTS AMBU A/S, AMBU INC.,  
AMBU LTD., and AMBU SDN. BHD.'s  
FIRST AMENDED ANSWER AND  
COUNTERCLAIMS**

Magistrate Judge Nita L. Stormes

Defendants Ambu A/S, Ambu Inc., Ambu Ltd., and Ambu Sdn. Bhd. (collectively  
“Ambu” or “Defendants”) by and through their attorneys hereby answer the First Amended  
Complaint for Patent Infringement (“the Amended Complaint”) of Plaintiffs The Laryngeal Mask  
Company Ltd. and LMA North America, Inc. (collectively “Plaintiffs”) as follows:

**JURISDICTION AND VENUE**

1. Ambu admits that the Amended Complaint purports to allege claims for patent infringement under the patent laws of the United States (Title 35 of the United States Code).
2. Ambu admits that this Court has subject matter jurisdiction, pursuant to 28 U.S.C. §§ 1331 and 1338(a).

3. Ambu admits that, for the purpose of this litigation, venue is proper in this Court under 28 U.S.C. §§ 1391(b), (c) and (d) and under 28 U.S.C. § 1400(b), and denies all other allegations contained in Paragraph 3.

#### **THE PARTIES**

4. Ambu is without sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 4, and therefore demand strict proof as to each allegation.

5. Ambu admits only that United States Patent No. 5,303,697 (“the ‘697 patent”) issued on April 19, 1994, and that United States Patent No. 7,156,100 (“the ‘100 patent”) issued on January 2, 2007. Ambu admits only that The Laryngeal Mask Company Ltd. (“LMC”) is listed as the owner by assignment of the ‘697 patent and the ‘100 patent. Upon information and belief, Ambu denies that the ‘697 and ‘100 patent were duly and lawfully issued.

6. Ambu is without sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 6 and therefore demand strict proof as to each allegation.

7. Admitted.

8. Ambu admits only that Ambu Inc. is a corporation organized and existing under the laws of the State of Maryland with its principal place of business at 6740 Baymeadow Drive, Glen Burnie, Maryland 21060, and demand strict proof as to all other allegations contained in Paragraph 8.

9. Ambu admits only that Ambu Ltd. is a corporation organized and existing under the laws of the People’s Republic of China with its principal place of business at Warehouse & Process Complex Building, No. C, Xiang Yu F.T.Z. Xiamen, 361006 China, and demand strict proof as to all other allegations contained in Paragraph 9.

10. Ambu admits only that Ambu Sdn. Bhd. Is a corporation organized and existing under the laws of Malaysia with its principal place of business at Lot 69B, Lintang Bayan Lepas 6, Phase IV, 11900 Penang, Malaysia, and demand strict proof as to all other allegations contained in Paragraph 10.

11. Ambu admits only that Ambu Inc. distributes, imports, offers to sell, and sells in the United States certain laryngeal mask airway devices that Plaintiffs allege infringe the ‘697 patent

1 and the '100 patent, including the Ambu AuraOnce, Aura40, AuraFlex, and AuraStraight brands  
2 of laryngeal mask airway devices. Ambu denies and demands strict proof of all other allegations  
3 contained in Paragraph 11.

4 12. Ambu admits only that Ambu Inc. does business in this judicial district. Ambu denies  
5 and demands strict proof of all other allegations contained in Paragraph 12.

6 **ANSWER TO FIRST CLAIM FOR RELIEF**

7 13. Ambu incorporates by reference their responses and allegations as set forth herein in  
8 Paragraphs 1 through 12 above.

9 14. Denied.

10 15. Ambu A/S admits that it had actual knowledge of the '697 patent prior to the alleged  
11 acts of infringement. Ambu Ltd. and Ambu Sdn. Bhd. deny that they had actual knowledge of the  
12 '697 patent prior to the alleged acts of infringement.

13 16. Denied.

14 17. Denied.

15 18. Denied.

16 **ANSWER TO SECOND CLAIM FOR RELIEF**

17 19. Ambu incorporates by reference their responses and allegations as set forth herein in  
18 Paragraphs 1 through 12 above.

19 20. Denied

20 21. Ambu A/S admits that it had actual knowledge of the '100 patent prior to the alleged  
21 acts of infringement. Ambu Ltd. and Ambu Sdn. Bhd. deny that they had actual knowledge of the  
22 '100 patent prior to the alleged acts of infringement.

23 22. Denied.

24 23. Denied.

25 24. Denied.

26 ///

27 ///

28 ///

**PRAYER FOR RELIEF**

Ambu hereby denies that Plaintiffs are entitled to judgment on any allegations or counts asserted in the Complaint or the First Amended Complaint and further deny that Plaintiffs are entitled to the relief requested in the Complaint or the First Amended Complaint.

Ambu further avers that any allegations not deemed to be specifically addressed in this Answer are hereby denied.

**AFFIRMATIVE DEFENSES**

**First Affirmative Defense**

25. Upon information and belief, Ambu has not infringed and does not infringe, either directly, contributively, or by inducement, any valid claim of the '697 or '100 patents (collectively "the Patents-in-Suit"), either literally or under the doctrine of equivalents.

**Second Affirmative Defense**

26. Upon information and belief, the Patents-in-Suit are invalid for failure to meet requirements of one or more sections of Title 35, United States Code, and/or Title 37, Code Federal Regulations, including but not limited to one or more of 35 U.S.C. §§ 102 and 103.

Ambu reserves the right to amend their defenses further as additional information is developed through discovery or otherwise.

**REQUEST FOR RELIEF**

Ambu prays that this Court enter judgment against Plaintiffs:

- A. Dismissing Plaintiffs' Amended Complaint with prejudice;
- B. Declaring that Plaintiffs recover nothing from Ambu;
- C. Awarding Ambu its costs and disbursements in this action; and
- D. Granting Ambu such other and further relief as this Court deems just and proper.

**COUNTERCLAIMS**

Ambu asserts the following counterclaims:

1. Ambu incorporates by reference its responses and allegations as set forth herein in Paragraphs 1 through 26 above.

///

**THE PARTIES**

2. Defendant and counterclaimant Ambu A/S is a corporation organized and existing under the laws of the Kingdom of Denmark with its principal place of business at Baltorpbakken 13, DK-2750 Ballerup, Denmark.

3. Defendant and counterclaimant Ambu Inc. is a corporation organized and existing under the laws of the State of Maryland with its principal place of business at 6740 Baymeadow Drive, Glen Burnie, Maryland 21060.

4. Defendant and counterclaimant Ambu Ltd. is a corporation organized and existing under the laws of the People's Republic of China with its principal place of business at Warehouse & Process Complex Building, No. C, Xiang Yu F.T.Z. Xiamen, 361006 China.

5. Defendant and counterclaimant Ambu Sdn. Bhd. is a corporation organized and existing under the laws of Malaysia with its principal place of business at Lot 69B, Lintang Bayan Lepas 6, Phase IV, 11900 Penang, Malaysia.

6. Plaintiff The Laryngeal Mask Company Ltd. ("LMC") has alleged in Paragraph 4 of the Amended Complaint that it is a corporation organized and existing under the laws of the Republic of Seychelles with its principal place of business at Le Rocher, Mahi, Seychelles.

7. Plaintiff LMA North America, Inc. ("LMNA") has alleged in Paragraph 6 of the Amended Complaint that it is a corporation organized and existing under the laws of the State of Nevada with its principal place of business at 4660 La Jolla Village Drive, San Diego, California, 92122, and that it is an affiliate of LMC.

8. Plaintiff LMC has alleged in Paragraph 5 of the Amended Complaint that it is the owner by assignment of the Patents-in-Suit.

9. Plaintiff LMNA has alleged in Paragraph 6 of the Amended Complaint that it is the exclusive licensee of the Patents-in-Suit.

///

///

///

///

**JURISDICTION AND VENUE**

10. These counterclaims arise under the Federal Declaratory Judgment Act and the Patent Laws of the United States, more particularly, under 28 U.S.C. §§ 2201 and 2202, and 35 U.S.C. §§ 100 et seq., respectively. This Court has jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338, and 2201.

11. There is an actual controversy between Ambu and Plaintiffs regarding the validity and infringement of the Patents-in-Suit.

12. Venue pursuant to 28 U.S.C. § 1391 in this judicial district for the following counterclaim of Ambu is proper because Plaintiffs have consented to this venue by asserting and filing claims of patent infringement against Ambu.

**COUNTERCLAIM FOR DECLARATORY JUDGMENT****First Counterclaim****(Non-Infringement)**

13. Upon information and belief, Defendants have not infringed and do not infringe, either directly, contributively, or by inducement, any valid claim of Patents-in-Suit, either literally or under the doctrine of equivalents.

**Second Counterclaim****(Invalidity)**

14. Upon information and belief, the Patents-in-Suit are invalid for failure to meet the requirements of one or more sections of Title 35, United States Code, and/or Title 37, Code of Federal Regulations, including but not limited to one or more of 35 U.S.C. §§ 102 and 103.

**COUNTERCLAIM FOR DAMAGES AND EQUITABLE RELIEF****FACTS****I. False Advertising that Ambu's Laryngeal Masks Cause Nerve Damage.**

15. LMA falsely claims in its advertising and other marketing materials that Ambu's laryngeal mask airway products cause nerve damage to patients, and are thus unsafe and inferior to LMA's products. Their false claims include misleading and deceiving characterizations of, and conclusions about, a study conducted by David Z. Ferson, M.D. ("the Ferson Study") in a

1 marketing brochure that LMA created, entitled “A Comparative Anatomical Study” (“the LMA  
2 Brochure”).

3 16. The Ferson Study does not reliably support LMA’s claims regarding the safety and  
4 inferiority of LMA’s products. Also, the LMA Brochure shows doctored and/or misleading  
5 helical computed topography (“CT”) scans. The Brochure further falsely suggests that the higher  
6 position of Ambu’s mask in the patient’s airway causes nerve damage because the mask could  
7 press on the hyoid bone which in turn presses on the hypoglossal nerve.

8 17. LMA has communicated and, on information and belief, continues to communicate,  
9 the falsehoods contained in the Brochure to Ambu’s customers and potential customers. LMA  
10 has distributed the Brochure to such customers by mail, the internet, and its sales force. Ambu is  
11 informed and believes that even during sales calls, visits, and other communications, LMA’s sales  
12 representatives have and continue to claim that Ambu’s laryngeal mask products cause nerve  
13 damage, often referring to the Ferson Study, in an effort to dissuade Ambu’s customers and  
14 potential customers from doing business with Ambu and divert them to LMA.

15 **II. LMA’s False and Misleading Statements that Ambu’s Customers Switched Back to**  
16 **LMA.**

17 18. LMA has communicated and, on information and belief, continues to communicate,  
18 false and misleading statements that several customers have switched from purchasing LMA’s  
19 laryngeal masks to Ambu’s laryngeal masks only to switch back to using LMA’s products. LMA  
20 has claimed and, on information and belief, continues to claim, that these customers switched  
21 back to LMA from Ambu for clinical and/or safety reasons, often referring to the Ferson Study  
22 and/or the false conclusions LMA has drawn from it. In addition to the Ferson Study being  
23 misleading, LMA’s claims that these customers have switched back to LMA after trying Ambu’s  
24 laryngeal mask products is false.

25 19. LMA has made such false claims to Ambu’s customers and potential customers  
26 through its sales representatives during sales calls, visits, emails, and other communications in  
27 order to dissuade these customers from doing business with Ambu and divert them to LMA.

28 ///

**(15 U.S.C. § 1125)**

22. LMA's conduct, as averred above, constitutes false or misleading descriptions of fact, and/or false, untrue or misleading representations of fact in violation of Lanham Act § 43(a), 15 U.S.C. § 1125(a). Such statements and advertising made by LMA are likely to deceive, and are intended to mislead those who see or hear them. Such deception is likely to influence the purchasing decision of those who read or hear these statements and advertisements.

24. LMA's conduct, as averred above, relates to Ambu's products.

26. On information and belief, such violation will continue unless LMA is enjoined by this Court. Ambu is therefore entitled to preliminary and permanent injunctive relief restraining LMA, its officers, agents and employees, and all persons acting in concert with it, from engaging in any further acts in violation of Section 43(a) of the Lanham Act.

///



**Fourth Counterclaim**

**(False Advertising Under California Business and Professions Code § 17500, et seq.)**

27. Ambu realleges and incorporates Counterclaim paragraphs 1-12 and 15-26 into this Counterclaim as if set forth herein.

28. LMA has, by its conduct alleged above, made false and misleading statements which were and are known or which, by the exercise of reasonable care, should have been known to LMA to be false and misleading in violation of Cal. Bus. & Prof. Code §§ 17500, *et seq.*

29. Such statements made by Defendants are likely to deceive, and intended to mislead those who see or hear them.

30. LMA's false and misleading statements are in violation and derogation of Ambu's rights. As a direct and proximate result of LMA's false and misleading statements, Ambu has suffered and will continue to suffer irreparable harm.

31. As a direct and proximate result of LMA's false and misleading statements, Ambu has suffered loss, damage and injury entitling Ambu to restitution of all amounts unlawfully gained by LMA, including disgorgement of profits earned by LMA.

32. LMA threatens to continue to engage in such unlawful acts, and unless and until restrained and enjoined by this Court, will do so. Ambu's remedy at law is not by itself adequate to compensate Ambu for the harm inflicted and threatened by LMA. Ambu is therefore entitled to preliminary and permanent injunctive relief restraining LMA, its officers, agents and employees, and all persons acting in concert with it, from engaging in any further acts in violation of Cal. Bus. & Prof. Code §§ 17500, *et seq.*

**Fifth Counterclaim**

**(Trade Libel)**

**(Cal. Civil Code § 45)**

33. Ambu realleges and incorporates Counterclaim paragraphs 1-12 and 15-32 into this Counterclaim as if set forth herein.

34. LMA knowingly made false statements to disparage and misrepresent the nature, character, and quality of Ambu's goods. These statements were made to third parties.

35. LMA's statements were made of and concerning Ambu's laryngeal mask products and were understood by those who read or heard the statements as such. LMA's statements disparaged Ambu's business products by falsely describing customer dissatisfaction with the products and mischaracterizing the functionality and safety of the products.

36. The purpose and effect of LMA's false statements have been to injure Ambu and to hinder Ambu's ability to market and sell its business products.

37. As a direct, proximate, and foreseeable result of LMA's intentional and wrongful publications and communications of false statements about Ambu's laryngeal mask products, LMA has disrupted Ambu's relationships with its customers, and thereby caused damages to Ambu, including, but not limited to, actual and potential loss of current and prospective customers and business.

38. As a direct and proximate result of LMA's unlawful acts herein alleged, Ambu has suffered and will continue to suffer irreparable harm. LMA threatens to continue to engage in such unlawful acts, and unless and until restrained and enjoined by this Court, will do so. Ambu's remedy at law is not by itself adequate to compensate LMA for the harm inflicted and threatened by Ambu. LMA is therefore entitled to preliminary and permanent injunctive relief restraining LMA, its officers, agents and employees, and all persons acting in concert with it, from engaging in any further acts in violation of Cal. Civil Code § 45.

### **Sixth Counterclaim**

#### **(Intentional Interference with Prospective Economic Relations)**

39. Ambu realleges and incorporates Counterclaim paragraphs 1-12 and 15-38 into this Counterclaim as if set forth herein.

40. Ambu has prospective economic relations with certain prospective customers to potentially purchase Ambu's laryngeal mask products. Such relationships have or had substantial likelihood of economic benefit for Ambu.

41. LMA knew of Ambu's prospective economic relations with these prospective customers, and in many cases were directly soliciting such customers for LMA's account.

///

42. LMA has intentionally interfered with these prospective economic relationships by inducing Ambu's prospective customers to refrain from purchasing Ambu's products. LMA's actions averred above were designed to disrupt Ambu's prospective economic relationships.

43. In doing so, LMA has acted wrongfully, through assertions of false and misleading information.

44. As a direct and proximate result of the intentional interference alleged above, Ambu's prospective economic relations with certain prospective customers have been disrupted, interrupted completely, or made more difficult or costly to achieve.

45. As a direct and proximate result of the intentional interference with prospective economic relations by LMA alleged above, Ambu has suffered loss, damage and injury in an amount to be proven at trial.

46. On information and belief, the intentional interference with prospective economic relations by LMA alleged above was conducted maliciously, oppressively, fraudulently and/or without regard to Ambu's rights. Accordingly, LMA is liable for punitive damages in an amount to be established at trial.

47. As a direct and proximate result of the intentional interference with prospective economic relations by LMA alleged above, Ambu has suffered and will continue to suffer irreparable harm. LMA threatens to continue to engage in such unlawful acts, and unless and until restrained and enjoined by this Court, will do so. Ambu's remedy at law is not by itself adequate to compensate Ambu for the harm inflicted and threatened by LMA. Ambu is therefore entitled to preliminary and permanent injunctive relief restraining LMA, its officers, agents and employees, and all persons acting in concert with it, from engaging in any further acts to interfere with, or to induce breaches of, Ambu's prospective economic relationships.

#### **Seventh Counterclaim**

**(Unfair Competition Under California Business and Professions Code § 17200, et seq.)**

48. Ambu realleges and incorporates Counterclaim paragraphs 1-12 and 15-47 into this Counterclaim as if set forth herein.

///

1           49.     LMA's acts as alleged herein constitute unfair competition in that such acts were and  
2     are unlawful, unfair, deceptive, and/or fraudulent business acts or practices in violation of Cal.  
3     Bus. & Prof. Code §§ 17200, *et. seq.* The unlawful business practices are described in detail in  
4     the foregoing paragraphs, and include:

5                 a.   Unlawful practices in the nature of conduct contrary to the federal false advertising  
6     statute, as averred above;

7                 b.   Unlawful practices in the nature of conduct contrary to the California false  
8     advertising statute, as averred above;

9                 c.   Unlawful practices in the nature of conduct contrary to the California trade libel  
10    statute, as averred above; and

11                d.   Unlawful practices in the nature of interference with prospective economic  
12    relations, as averred above.

13           50.     In addition, LMA has engaged in deceptive business practices through the false and  
14    misleading statements communicated to Ambu's customers as averred above.

15           51.     In addition, LMA has engaged in unfair business practices by intentionally diverting  
16    Ambu's customers through the false and misleading statements communicated to Ambu's  
17    customers as averred above.

18           52.     As a direct and proximate result of LMA's unfair competition, Ambu has suffered  
19    loss, damage and injury entitling Ambu to restitution of all amounts unlawfully gained by LMA,  
20    including disgorgement of profits earned by LMA.

21           53.     As a direct and proximate result of LMA's unfair competition, Ambu has suffered and  
22    will continue to suffer irreparable harm. LMA threatens to continue to engage in such unlawful  
23    acts, and unless and until restrained and enjoined by this Court, will do so. Ambu's remedy at  
24    law is not by itself adequate to compensate Ambu for the harm inflicted and threatened by LMA.  
25    Ambu is therefore entitled to preliminary and permanent injunctive relief restraining LMA, its  
26    officers, agents and employees, and all persons acting in concert with it, from engaging in any  
27    further acts in violation of Cal. Bus. & Prof. Code §§ 17200, *et seq.*

28    ///

**REQUEST FOR RELIEF**

Ambu Inc., Ambu A/S, Ambu Ltd., and Ambu Sdn. Bhd. pray that this Court enter judgment against Plaintiffs:

A. Declaring that Ambu Inc., Ambu A/S, Ambu Ltd., and Ambu Sdn. Bhd. have not infringed, either directly or indirectly, and are not infringing either directly or indirectly, any valid claim of the Patents-in-Suit;

B. Enjoining Plaintiffs, their officers, agents, servants, employees, attorneys, and representatives, and any successors and assigns thereof, from charging or asserting infringement of any claim of the Patents-in-Suit against Ambu Inc., Ambu A/S, Ambu Ltd., or Ambu Sdn. Bhd. or anyone in privity with Ambu Inc., Ambu A/S, Ambu Ltd., or Ambu Sdn. Bhd.;

C. Declaring that the claims of the Patents-in-Suit are invalid;

D. Granting Ambu Inc., Ambu A/S, Ambu Ltd., and Ambu Sdn. Bhd. an award of general damages for injury to reputation according to proof.

E. Granting Ambu Inc., Ambu A/S, Ambu Ltd., and Ambu Sdn. Bhd. restitution and disgorgement of any profits of Plaintiffs from their wrongful conduct according to proof.

F. For attorneys' fees according to applicable statutes.

G. Granting Ambu Inc., Ambu A/S, Ambu Ltd., and Ambu Sdn. Bhd. preliminary and permanent injunctive relief against LMA, its officers, employees, agents, or anyone working for, in concert with or on behalf of it, or anyone who receives actual notice of the injunction:

1. To refrain from publishing, circulating, e-mailing, making available, or otherwise distributing the Brochure, or any other document that contains false, misleading, and/or deceptive statements regarding Ambu's laryngeal mask products;
2. To refrain from, directly or indirectly, making any false or misleading representations of fact in commerce concerning Ambu's laryngeal mask products, either orally or in writing;
3. To refrain from circulating, e-mailing, making available, or otherwise distributing any advertisement, or any other document that contains false, misleading, and/or deceptive statements regarding customers switching to LMA from Ambu; and



1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28

**CERTIFICATE OF SERVICE**

The undersigned hereby certifies that all counsel of record who are deemed to have consented to electronic service are being served with a copy of DEFENDANTS AMBU A/S, AMBU INC., AMBU LTD., and AMBU SDN. BHD.'s FIRST AMENDED ANSWER AND COUNTERCLAIMS via the Court's CM/EFC system per Local Rule 5.2 on August 25, 2008.

By: /s/ Dennis Faigal

---

Dennis Faigal  
E-mail: dfaigal@fenwick.com

FENWICK & WEST LLP  
ATTORNEYS AT LAW  
MOUNTAIN VIEW